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Attn: Mr. Matthew Forward

Dear Sirs

MERLIN MD PTE LTD
PCT APPLICATION NO. PCT/SG2004/000319
"IMPLANTABLE MEDICAL DEVICES WITH GOOD VISIBILITY AND MECHANICAL PROPERTIES"

We refer to the fourth Written Opinion dated 26 July 2005.

The examiner asserts that claims 15, 16 and 19 to 27 are not novel and/or not inventive when compared to the cited documents.

We submit an amended set of claims. Claim 15 has been amended by limiting the composition of the platinum:iridium and platinum:tungsten alloys as previously incorporated for claim 1. Therefore, we respectfully submit that claim 15 and its dependent claims are now clearly distinguishable from the cited documents, as the specific % composition for any of these platinum alloys for the stent is not taught or disclosed by the cited documents. As previously submitted, the selection of these specific platinum alloys provides distinct advantages not enjoyed by the prior art.

Minor cosmetic amendments have been made to claims 17 and 18 also.

Accordingly, we look forward to receiving a favourable International Preliminary Examination Report in due course.

Yours faithfully,



James Wan
 Patent Attorney
ALBAN TAY MAHTANI & DE SILVA

Encs – amended claims (clean version, 4pgs)
 amended claims (mark-up version, 4pgs)

WE CLAIM:

1. A stent for insertion into a bodily vessel for treatment of an aneurysm or ischemic diseases,
wherein the stent is made from a platinum alloy selected from the group consisting of platinum:iridium alloy, platinum:tungsten alloy, platinum:rhodium:ruthenium alloy, platinum:rhodium alloy and platinum:nickel alloy; and
wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium;
wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten;
wherein the platinum:rhodium:ruthenium alloy has a composition of about 70-85% of platinum, 10-20% of rhodium and 3-10% of ruthenium;
wherein the platinum:rhodium alloy has a composition of about 60-80% of platinum and 20-40% of rhodium; and
wherein the platinum:nickel alloy has a composition of about 80-90% of platinum and 10-20% of nickel.
2. The stent according to claim 1, wherein the stent comprises a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween, said generally tubular structure expandable from a first position to a second position, wherein said tubular structure expands radially outwardly to the second position such that the exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel.
3. The stent according to claim 1, wherein the stent is a self-expandable stent.
4. The stent according to claim 1, wherein the platinum:tungsten alloy has a composition of about 90-95% of platinum and 5-10% of tungsten.
5. The stent according to claim 1, wherein the platinum:rhodium:ruthenium alloy has a composition of about 75-80% of platinum, 12-18% of rhodium and 5-10% of ruthenium.
6. The stent according to claim 1, wherein the platinum:rhodium alloy has a composition of about 65-75% of platinum and 25-35% of rhodium.

7. The stent according to claim 10, wherein the platinum:nickel alloy has a composition of about 85-90% of platinum and 10-15% of nickel.

8. The stent according to claim 1, wherein the stent is made from a wire of platinum:tungsten, platinum:iridium alloys, and welded to a predetermined tubular mesh.

9. The stent according to any one of claims 1 to 8, wherein the stent has a sidewall thickness of less than 0.0035".

10. The stent according to any one of claim 1 to 9, wherein the surface of the stent is modified by passive coatings.

11. The stent according to claim 10, wherein the coating is iridium oxide or titanium nitrate.

12. The stent according to claim 10, wherein the stent is coated with an external layer containing a pharmaceutically effective amount of therapeutic substances.

13. The stent according to claim 1, further comprising markers to enhance visibility and radiopacity of the device.

14. The stent according to claim 13, wherein the markers include end markers or center markers.

15. An implantable endovascular device for insertion into a bodily vessel to treat ischemic and hemorrhagic stroke, the device comprising:

a wire structure made from a platinum alloy selected from the group consisting of platinum:iridium alloy and platinum:tungsten alloy, the structure being expandable from a first position to a second position, and said structure expands radially outwardly to the second position such that an exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel;

wherein the wire structure is formed by welding tubular shaped wire sections together and the exterior surface of the wire structure is defined by the welded wire sections;

wherein the device is longitudinally flexible, the flexibility being such that it is greater than a delivery catheter to deliver the device into the bodily vessel; and

wherein the longitudinal flexibility of the device is defined by deflection of the device from a neutral line to 1mm when there is a force less than 8 grams;

wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium; and

wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten.

16. The device according to claim 15, wherein the welding is laser welding.
17. A delivery system for inserting a ~~device-an implantable medical device~~stent according to claim 1, within a bodily vessel, wherein the ~~device~~stent is expandable by balloon inflation, the delivery system comprising a balloon delivery catheter and the ~~device~~stent, wherein the ~~expandable medical device~~stent is mounted onto the balloon of the delivery catheter.
18. A delivery system for inserting an implantable medical device according to claim 1, within a bodily vessel, wherein the ~~device~~stent is self-expandable, the delivery system comprising a delivery catheter and the ~~device~~stent, wherein the ~~device~~stent is mounted onto a distal portion of the delivery catheter.
19. The device according to claim 15, wherein the device is deployed at a pressure equal to or below 4atm.
20. The device according to claim 15, wherein the structure of the device provides a normalized radial force 18 to 19 grams per mm of length.
21. The device according to claim 20, wherein the structural support of the device provides 3 to 4% of deflection of the structure of the device together with natural pulsing of an intracranial vessel wall.
22. The device according to claim 15, wherein the device has a profile in a compressed delivery form of 0.020 inches.
23. The device according to claim 15, wherein the device has a profile between 0.014 to 0.016 inches and the profile of the device in an uncompressed delivery form is between 0.020 to 0.022 inches.
24. The device according to claim 15, wherein the device has uniform material distribution and wall coverage for providing support to a bodily vessel.

25. The device according to claim 15, wherein the ratio of the material is in the range of 12 to 16%, the range being dependent on the diameter of deployment.

26. The device according to claim 15, wherein the device comprises struts, the struts having a thickness and width less than or equal to 0.0028 inches.

27. The device according to claim 15, wherein the device has a surface to length ratio between 1.1 to 1.3mm²/mm to provide minimal vessel injury score.

WE CLAIM:

1. A stent for insertion into a bodily vessel for treatment of an aneurysm or ischemic diseases,
wherein the stent is made from a platinum alloy selected from the group consisting of platinum:iridium alloy, platinum:tungsten alloy, platinum:rhodium:ruthenium alloy, platinum:rhodium alloy and platinum:nickel alloy; and
wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium;
wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten;
wherein the platinum:rhodium:ruthenium alloy has a composition of about 70-85% of platinum, 10-20% of rhodium and 3-10% of ruthenium;
wherein the platinum:rhodium alloy has a composition of about 60-80% of platinum and 20-40% of rhodium; and
wherein the platinum:nickel alloy has a composition of about 80-90% of platinum and 10-20% of nickel.
2. The stent according to claim 1, wherein the stent comprises a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween, said generally tubular structure expandable from a first position to a second position, wherein said tubular structure expands radially outwardly to the second position such that the exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel.
3. The stent according to claim 1, wherein the stent is a self-expandable stent.
4. The stent according to claim 1, wherein the platinum:tungsten alloy has a composition of about 90-95% of platinum and 5-10% of tungsten.
5. The stent according to claim 1, wherein the platinum:rhodium:ruthenium alloy has a composition of about 75-80% of platinum, 12-18% of rhodium and 5-10% of ruthenium.
6. The stent according to claim 1, wherein the platinum:rhodium alloy has a composition of about 65-75% of platinum and 25-35% of rhodium.

7. The stent according to claim 10, wherein the platinum:nickel alloy has a composition of ~~about 85-90% of platinum and 10-15% of nickel.~~

8. The stent according to claim 1, wherein the stent is made from a wire of platinum:tungsten, platinum:iridium alloys, and welded to a predetermined tubular mesh.

9. The stent according to any one of claims 1 to 8, wherein the stent has a sidewall thickness of less than 0.0035".

10. The stent according to any one of claim 1 to 9, wherein the surface of the stent is modified by passive coatings.

11. The stent according to claim 10, wherein the coating is iridium oxide or titanium nitrate.

12. The stent according to claim 10, wherein the stent is coated with an external layer containing a pharmaceutically effective amount of therapeutic substances.

13. The stent according to claim 1, further comprising markers to enhance visibility and radiopacity of the device.

14. The stent according to claim 13, wherein the markers include end markers or center markers.

15. An implantable endovascular device for insertion into a bodily vessel to treat ischemic and hemorrhagic stroke, the device comprising:

a wire structure made from a platinum alloy selected from the group consisting of platinum:iridium alloy and platinum:tungsten alloy, the structure being expandable from a first position to a second position, and said structure expands radially outwardly to the second position such that an exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel;

wherein the wire structure is formed by welding tubular shaped wire sections together and the exterior surface of the wire structure is defined by the welded wire sections;

wherein the device is longitudinally flexible, the flexibility being such that it is greater than a delivery catheter to deliver the device into the bodily vessel;

wherein the longitudinal flexibility of the device is defined by deflection of the device from a neutral line to 1mm when there is a force less than 8 grams;

wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium; and

wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten.

16. The device according to claim 15, wherein the welding is laser welding.
17. A delivery system for inserting a stent according to claim 1, within a bodily vessel, wherein the stent is expandable by balloon inflation, the delivery system comprising a balloon delivery catheter and the stent, wherein the stent is mounted onto the balloon of the delivery catheter.
18. A delivery system for inserting a stent according to claim 1, within a bodily vessel, wherein the stent is self-expandable, the delivery system comprising a delivery catheter and the stent, wherein the stent is mounted onto a distal portion of the delivery catheter.
19. The device according to claim 15, wherein the device is deployed at a pressure equal to or below 4atm.
20. The device according to claim 15, wherein the structure of the device provides a normalized radial force 18 to 19 grams per mm of length.
21. The device according to claim 20, wherein the structural support of the device provides 3 to 4% of deflection of the structure of the device together with natural pulsing of an intracranial vessel wall.
22. The device according to claim 15, wherein the device has a profile in a compressed delivery form of 0.020 inches.
23. The device according to claim 15, wherein the device has a profile between 0.014 to 0.016 inches and the profile of the device in an uncompressed delivery form is between 0.020 to 0.022 inches.
24. The device according to claim 15, wherein the device has uniform material distribution and wall coverage for providing support to a bodily vessel.

25. The device according to claim 15, wherein the ratio of the material is in the range of 12 to ~~16%, the range being dependent on the diameter of deployment.~~

26. The device according to claim 15, wherein the device comprises struts, the struts having a thickness and width less than or equal to 0.0028 inches.

27. The device according to claim 15, wherein the device has a surface to length ratio between 1.1 to 1.3mm²/mm to provide minimal vessel injury score.